Remarks

Claims 1-18, 22-27, 39-59, 63-68, 80-103, 107-112, 129-135 and 139-156 are canceled herein without prejudice. Applicant reserves the right to pursue the subject matter of these claims in divisional or continuing applications. Claims 19-21, 28-38, 60-62, 69-79, 104-107, 113-128 and 136-138 are pending in the application.

I. Double Patenting

Claims 19, 28, 30, 32, 34-38, 60, 69-71, 73, 75, 104, 113-116, 118-121 and 126-128 stand rejected on the grounds of obviousness-type double patenting as being unpatentable over claims 44-55 of U.S. Patent No. 6,720,140. (Office Action, page 3.) Applicants respectfully disagree but have amended the claims to facilitate prosecution.

Independent claims 19, 60 and 104 are amended herein to recite "a fusion protein that comprises SEQ ID NO:6." Support for the amendment is found, *inter alia*, in Figures 7, 8, 10 and 11. Claims 44-55 of U.S. Patent No. 6,720,140 are directed, in part, to a method of in vitro cloning of nucleic acid molecules using site-specific recombination. U.S. Patent No. 6,720,140 does not teach or suggest a fusion protein comprising SEQ ID NO:6 nor does it teach or suggest the use of toposiomerase for cloning nucleic acid molecules as do independent claims 60 and 104 of the present application. Therefore applicant asserts that the present invention is patentably distinct from claims 44-55 of U.S. Patent No. 6,720,140 and respectfully request reconsideration and withdrawl of the obviousness-type double patenting rejection of claims 19, 28, 30, 32, 34-38, 60, 69-71, 73, 75, 104, 113-116, 118-121 and 126-128.

II. 35 U.S.C. § 112, First Paragraph

Claims 19, 35, 104 and 121 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. (Office action, page 8.) Applicants respectfully disagree but have amended the claims to facilitate prosecution.

As amended herein, claims 35 and 121 no longer reference "mutants, variants and derivatives of the recombination sites." Applicant asserts that amended claims 35 and 121 are fully supported by the specification and respectfully request reconsideration and withdrawal the rejection of claims 19, 35, 104 and 121 under 35 U.S.C. § 112, first paragraph.

Claims 19-38, 60-79, 104-128 and 136-138 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to provide enablement of all "mutants, variants and derivatives" of the recombination sites. (Office action, page 10.) Applicants respectfully disagree but have amended the claims to facilitate prosecution.

As amended herein, claims 35 and 121 no longer reference "mutants, variants and derivatives of the recombination sites." Applicant asserts that amended claims 35 and 121 are fully enabled by the specification and respectfully request reconsideration and withdrawal the rejection of claims 19-38, 60-79, 104-128 and 136-138 under 35 U.S.C. § 112, first paragraph.

III. 35 U.S.C. § 112, Second Paragraph

Claims 19, 35, 60-79 and 104-128 stand rejected under 35 U.S.C. § 112, second paragraph, for being indefinite. (Office Action, page 13.) Applicants respectfully disagree but have amended the claims to facilitate prosecution.

As amended herein, claims 60 and 104 now recite a "composition" comprising a second nucleic acid and a topoisomerase. Applicant asserts that a composition may comprise both a nucleic acid and an enzyme and therefore the amended claims particularly point and distinctly claim the subject matter the applicant regards as the invention.

As noted above, as amended herein claims 35 and 121 no longer recite "mutants, variants and derivatives of the recombination sites." Therefore, the Examiner's concerns regarding metes and bounds of the claims are rendered moot.

In view of the amendments and arguments above, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 19, 35, 60-79 and 104-128 under 35 U.S.C. § 112, second paragraph.

IV. 35 U.S.C. § 102

Claims 19, 28, 30-32 and 34-37 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hartley *et al.* (*Genome Research 10*:1788-1795 2000) (Office Action, page 13.)

Claims 60, 69-70, 72-73 and 75-79 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Heyman *et al.* (*Genome Research 9*:383-392 1999) (Office action, page 14.)

Claims 19, 28, 30-32, 34-38, 60, 69-73, 75-79, 104 and 113-128 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Hartley *et al.* (U.S. Patent No. 6,277,608) (Office

action, page 15.) Applicants respectfully disagree but have amended the claims to facilitate prosecution.

In order to anticipate, a single reference must disclose "each and every limitation of the claimed invention." (*Helifix Ltd. v. Blok-Lok, Ltd.*, 208, F.3d 1339, 1346 (Fed. Cir. 2000).) As amended herein, independent claims 19, 60 and 104 now recite "encodes a fusion protein that comprises SEQ ID NO:6." Support for this amendment is found, *inter alia*, in Figures 7, 8, 10 and 11. Neither Hartley *et al.*, Heyman *et al.* or U.S. Patent No. 6,277,608 disclose methods for producing a polynucleotide that "encodes a fusion protein that comprises SEQ ID NO:6." Because none of the cited references discloses "each and every limitation of the claimed invention," the cited references do not anticipate the claims as amended herein. Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 19-38, 60-79, 104-128 and 136-138 under 35 U.S.C. § 102(b) and/or 102(e).

V. ***35 U.S.C. § 103***

Claims 19-27, 33, 60-68, 74 and 104-112 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley *et al.* (U.S. Patent No. 6,277,608) and further in view of Hearn *et al.* (*J. Mol. Recognit. 14*:323-369 2001), Cronan (*J. Biol. Chem. 265*:10327-10333 1990) and Airenne *et al.* (Protein Expression and Purification 17:139-145 1999). (Office action, page 19.)

In order to establish a *prima facie* case of obviousness, three basic criteria must be met. (*See* Manual of Patent Examining Procedure (MPEP) § 2142 (eighth edition, revision 5, August 2006).) First, there must be some suggestion or motivation, either in the

references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The cited references, U.S. Patent No. 6,277,608, Hearn *et al.*, Cronan and Airenne *et al.* discloses the production of nucleic acid molecules using site-specific recombination and topoisomerase and the use of fusion proteins with amino acid sequence tags and protease cleavage sites. These references do not disclose the use of SEQ ID No:6 as an amino acid sequence tag in a fusion protein. Because the cited references do not teach all the elements of the claims, Applicant asserts that the present invention as claimed is not obvious in view of U.S. Patent No. 6,277,608, Hearn *et al.*, Cronan and Airenne *et al.* Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 19-27, 33, 60-68, 74 and 104-112 under 35 U.S.C. 103(a).

Conclusion

Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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